participation in its review of the application. To meet this requirement, the agency is providing notice that The Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, has filed an application requesting approval for the export of the human drug CAVERJECT Sterile Powder (Alprostadil for Injection) 20µg/mL vials to Sweden via Belgium. The product is to be used for the treatment of erectile dysfunction. The application was received and filed in the Center for Drug Evaluation and Research on May 5, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by June 12, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: May 18, 1995.

Betty L. Jones,

Acting Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–13352 Filed 5–31–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0124]

Medical Devices; Third Party Review of Selected Premarket Notifications; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss a proposed pilot program for third party review of selected premarket notifications. The purpose of the workshop is to provide information on the pilot program and to obtain public comments and suggestions that may help FDA refine its plans for third party review of selected premarket notifications. This workshop is one aspect of FDA's efforts in pursuit of the reinventing Government goals of the National Performance Review as well as the promotion and protection of the public health.

DATES: The workshop will be held on June 19, 1995, from 9 a.m. to 4:30 p.m. Submit written notices of participation by June 9, 1995. Participants and other persons who want to be heard must be present by 9 a.m. Submit written comments by July 7, 1995. There is no registration fee for this workshop. Interested persons are encouraged to register early because space is limited.

ADDRESSES: The workshop will be held at the Doubletree Hotel Rockville (formerly, the Holiday Inn Crowne Plaza), 1750 Rockville Pike, Rockville, MD. A limited number of overnight accommodations have been reserved at the Doubletree Hotel Rockville. Attendees requiring overnight accommodations may contact the hotel at 301–468–1100 and reference FDA meeting group GVL. Reservations will be confirmed at the group rate based on availability.

A registration form for the workshop may be obtained by contacting Sociometrics, Inc., 8300 Colesville Rd., Suite 550, Silver Spring, MD 20910, 301–608–2151 or 1–800–729–0890 (FAX 301–608–3542). Persons with disabilities who require special assistance to attend or participate in the workshop can be accommodated if advance notification is provided. If you have a disability that affects your attendance at, or participation in, this meeting, please contact Ed Rugenstein, Sociometrics, Inc., in writing and identify your needs. The availability of appropriate accommodations cannot be assured unless prior written notification is provided.

Written comments regarding the pilot program may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Those persons who wish to make a presentation must submit a written notice of participation to the Dockets Management Branch (address above), identified with the docket number found in brackets in the heading of this document, including their name, address, telephone number, business affiliation, a brief summary of the presentation, and an estimate of the amount of time required to make their comments. FDA requests that individuals or groups having similar interests consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests.

Transcripts of the workshop will be available from the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6310 or FAX 301–443–1726.

FOR FURTHER INFORMATION CONTACT: Eric J. Rechen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, FAX 301–594–2977.

SUPPLEMENTARY INFORMATION:

I. Background

On April 6, 1995, FDA announced a limited pilot program to test the usefulness and practicality of third party review of medical devices. Under the proposed pilot, FDA will designate private sector organizations to review premarket notifications under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (hereinafter referred to as 510(k)'s). This initiative will provide an alternative to FDA review and is one aspect of FDA's efforts in pursuit of the reinventing Government goals of the National Performance Review. FDA expects the pilot program will begin early in fiscal year 1996.

FDA's primary concern remains the promotion and protection of the public health. The proposed pilot will include checks and balances to ensure a high level of quality in the review of 510(k)'s.

II. Outline of the Proposed Third Party Review Pilot

At this time, FDA has not determined the final form of its pilot third party review process. The initial pilot program will be restricted to third party review, but not clearance, of 510(k)'s. During the pilot, the third party will make a recommendation to FDA. FDA will then make a decision based on the third party's documented review. The purpose of the pilot is to test the feasibility of third party review, including the willingness of qualified third parties to participate, and the quality and timeliness of third party reviews.

Industry participation in the pilot program will be voluntary. An applicant who does not wish to participate will be able to continue to submit 510(k)'s to FDA. The pilot will last 2 years, and will be evaluated by FDA in the second year.

FDA anticipates that the pilot program will be limited to FDA-designated class I and II devices that involve low-to-moderate risk. The pilot

will exclude 510(k)'s that require clinical data for a decision. Clear review criteria must also be available, in the form of FDA guidance documents, consensus standards, or other appropriate assessment tools. FDA has prepared a preliminary list of devices that may be included in the pilot (see section IV. of this document for information on obtaining a copy).

Third party review organizations will be individually accepted by FDA. FDA will establish and apply requirements covering personnel qualifications as well as controls over potential conflicts of interest. FDA believes it is essential that third party review organizations maintain adequate independence from the device industry. FDA is also considering additional safeguards to ensure the quality and impartiality of third party reviews. Among the safeguards being considered are: FDA examination, acceptance, and oversight of third party review organizations; provision of training and standard operation procedures for third parties; audits of third party reviews; having FDA personnel serve as on site advisors to third party review bodies; and database checks to track ongoing reviews.

FDA expects that applicants who submit a 510(k) to a third party during the pilot will pay a fee directly to the third party. FDA does not expect to take part in setting fees, but rather intends to leave this to be negotiated between the third party review organization and the applicant.

The full range of general controls (current good manufacturing practices (CGMP's), medical device reporting, prohibition against adulteration and misbranding, etc.) and, where appropriate, special controls (device tracking, postmarket surveillance, etc.) will be applicable to devices included in the pilot program.

III. Purpose and Tentative Agenda of the Workshop

The purpose of the workshop is to obtain public comments and suggestions that will help FDA refine its plans for a pilot program for third party review of selected 510(k)'s.

Joseph A. Levitt, Deputy Director for Regulations and Policy, Center for Devices and Radiological Health, FDA, will preside. Mr. Levitt will be assisted by other FDA officials.

FDA will open the workshop with a summary of the framework for the proposed pilot program. This presentation will provide information on the impetus, objectives, and scope of the proposed pilot program. Following FDA's presentation, other participants will make presentations. After reviewing the notices of participation, FDA will allocate the time available for presentations among those persons who properly file a written notice of participation. FDA will schedule each appearance and will notify each participant by mail or telephone of the time allotted to him or her and the approximate time his or her presentation is scheduled to begin. The full schedule will be available at the workshop and will subsequently be placed on file in the Dockets Management Branch under the docket number found in brackets in the heading of this document. Time permitting, the workshop will also include an opportunity for interested persons who did not submit a notice of participation to make brief statements or comments. The workshop will then proceed to a panel discussion of specific issues that FDA must resolve before third party reviews of 510(k)'s can begin. Among the topics to be discussed are the following: Which devices should be eligible for third party review; criteria for selection or acceptance of private sector organizations to perform reviews, including conflict of interest protections; safeguards necessary to ensure a fair and impartial review by a third party; and funding of third party reviews.

FDA is making available a list of specific topics for written comment and discussion at the workshop. (See section IV. of this document for information on how to obtain a copy.)

The workshop is informal, and the rules of evidence will not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question participants at the conclusion of their presentations.

IV. Obtaining Additional Information on the Workshop

Information on the June 19, 1995, workshop, including a more detailed listing of the topics and issues on which FDA is inviting comment and a list of the devices proposed for inclusion in the pilot, can be obtained from the Dockets Management Branch (address above) or by calling FDAs Facts-on-Demand system. The Facts-on-Demand system can be reached by calling 1–800–899–0381 or 301–827–0111 on a touch-tone phone. Follow the instructions provided, and request DSMA shelf number 150. The requested materials will be sent by FAX.

Dated: May 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–13294 Filed 5–26–95; 10:22 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

RIN 0905–ZA89

Program Announcement and Proposed Review Criteria for Grants for the Minority Faculty Fellowship Program for Fiscal Year 1995

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1995 Grants for the Minority Faculty Fellowship Program (MFFP) under the authority of section 738(b), title VII of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408, dated October 13, 1992. Comments are invited on the proposed review criteria.

Approximately $210,000 will be available in FY 1995 for this program. It is anticipated that $210,000 will be available to support about five competing awards to schools and other eligible entities averaging $42,000 which will cover the cost of the following: stipend in an amount not exceeding 50 percent of the regular salary of a similar faculty member or $30,000, which ever is less, and tuition, fees and travel, where appropriate.

Purpose

The purpose of the MFFP is to increase the number of underrepresented minority faculty members in health professions schools, i.e., schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, health administration, clinical psychology, and other public or private nonprofit health or educational entities.

Specifically, these grant awards are intended to allow institutions an opportunity to provide a fellowship to individuals who have the potential for teaching, administering programs, or conducting research as faculty members. Institutions must demonstrate a commitment and ability to identify, recruit, and select underrepresented minorities in health professions. The institutions' training programs provide the fellows with the techniques and skills needed to secure an academic career including competence in: pedagogical skills, research methodology, development of research